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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/600,911 | 08/01/2000 | JERRY KANELLOS | 47-139 | 2571 |

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| EXAMINER | |
|---|---|
| SNEDDEN, SHERIDAN | |

| ART UNIT | PAPER NUMBER |
|---|---|
| 1653 | 14 |

DATE MAILED: 01/14/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 09/600,911 | KANELLOS ET AL. | |
| | Examiner | Art Unit | |
| | Sheridan K Snedden | 1653 | |

*-- The MAILING DATE of this communication appears on th cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *03 October 2002 and 18 September 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-22* is/are pending in the application.

4a) Of the above claim(s) *none* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-22* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *11* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

## DETAILED ACTION

1. Applicant's amendment of claims 1, 14, 19 and 20 and addition of new claims 21 and 22 in Paper No. 12, filed September 18, 2002 is acknowledged. Applicant's amendment of claim 14 in Paper No. 13, filed October 3, 2002 is acknowledged. Claims 1-22 are pending.

### *Claim Rejections - 35 USC § 112*

2. Previous rejections under second paragraph of 35 U.S.C. 112 have been withdrawn.

### *Claim Objections*

Claims 1 and 14to because of the wording "fibrinogen containing precipitate," which should read "precipitate containing fibrinogen."

### *Claim Rejections - 35 USC § 102*

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-5, 7-12, and 17-18 are rejected under 35 U.S.C. 102(b) as being anticipated by Winkleman (US Patent 4,789,733). Winkleman teaches the enrichment of fibrinogen and Factor VIII from blood plasma fraction, especially cryoprecipitate (see abstract; regarding claim 2, 15). This was achieved by the addition of at least 0.15 mg/ml of sulphated polysaccharide, especially

heparin (regarding claim 7-9), to form a precipitate containing fibrinogen (see abstract; regarding claims 1, step (i)). In the paragraph bridging columns 5 and 6, Winkleman teaches this precipitate containing fibrinogen may be further processes to extract fibrinogen. In examples 23 and 24, Winkleman teaches how to further process a precipitate containing fibrinogen. Winkleman extracts fibrinogen (91% yield based on activity) from a precipitate using a saline solution (at least 0.1M NaCl or sodium chloride; regarding claims 3-5) and 2.2 M glycine (example 23; regarding claims 1, step (ii)). In example 24, the extracted FVII and fibrinogen is gel purified, lyophilized and heated for viral inactivation (regarding claims 11-12 and 17-18). The gel purification step would have removed SPS from the preparation. Thus, the reference anticipates the claimed invention.

### *Claim Rejections - 35 USC § 103*

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Winkleman (US Patent 4,789,733), in view of Mosesson and Altieri *et al.* (US 20020131970 A1).

Winkleman teaches the enrichment of fibrinogen and Factor VIII from blood plasma fraction, especially cryoprecipitate (see abstract; regarding claim 2, 15, 19, and 21). This was achieved by the addition of at least 0.15 mg/ml of sulphated polysaccharide, especially heparin (regarding claim 7-9), to form a precipitate containing fibrinogen (see abstract; regarding claims

1 and 14, step (i)). In the paragraph bridging columns 5 and 6, Winkleman teaches this precipitate containing fibrinogen may be further processes to extract fibrinogen. In examples 23 and 24, Winkleman teaches how to further process a precipitate containing fibrinogen. Winkleman extracts fibrinogen (91% yield based on activity) from a precipitate using a saline solution (at least 0.1M NaCl or sodium chloride; regarding claims 3-5) and 2.2 M glycine (example 23; regarding claims 1 and 14, step (ii)). In example 24, the extracted FVII and fibrinogen is gel purified, lyophilized and heated for viral inactivation (regarding claims 11-12 and 17-18). The gel purification step would have removed SPS from the preparation. Thus, the reference anticipates the claimed invention.

Winkleman does not expressly teach the use of ε-aminocaproic acid (claim 6), NaCl concentrations of at least 0.2 M (claims 16, 20 and 22), the use of chromatographic techniques for the further purification of fibrinogen (claim 13), or the additional step of purifying fibrinogen away from fibronectin or Factor VIII (claim 14(iii)).

Mosesson teach the use of ε-aminocaproic acid in the preparation of fibrinogen. ε-aminocaproic acid is taught as enhancing the yield of fibrinogen by altering the solubility characteristics of fibrinogen. Additionally, Mosesson teaches the use of 0.3M NaCl in the preparation of fibrinogen.

Altieri *et al.* teach the use of a Sepharose.TM. 4B column (Pharmacia LKB, Piscataway, N.J.) to remove any possible contamination of the purified fibrinogen with fibronectin, the purified fibrinogen preparation which resulted in fibronectin-free fibrinogen (regarding claims 13 and 14(iii)).

Taken together, the above reference teaches the method of obtaining fibrinogen consistant with the method steps and reagents of claims 1-22. Thus, it would have been obvious to the person of ordinary skill in the art at the time the invention was made to prepare fibrinogen by first precipitating cryoprecipitate with sulphated polysaccharide precipitation, to extract fibrinogen using a saline solution and the to further purify the fibrinogen away from fibronectin. A person of ordinary skill in the art would have been motivated, and would have expected success, to combine the above steps and reagent as each step and reagents are well described in the prior art in methods of extraction and purification of fibrinogen. Thus, the claimed invention was within the ordinary skill in the art to make and use at the time it was made and was as a whole, *prima facie* obvious.

***Conclusion***

5. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sheridan K Snedden whose telephone number is (703) 305-4843. The examiner can normally be reached on Monday - Friday, 8:30 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on (703) 308-2923. The fax phone number for regular communications to the organization where this application or proceeding is assigned is (703) 746-3975.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

SKS
January 13, 2003

SKS

CHRISTOPHER S. F. LOW
SUPERVISORY PATENT EXAMINER
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